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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,408	08/08/2006	Kai Kin Lau	70026930-0024	9419

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EXAMINER
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SAMALA, JAGADISHWAR RAO

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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10/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/552,408

Applicant(s)

LAU, KAI KIN

Examiner

Jagadishwar R. Samala

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/25/2006</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### **Status of Application**

1. Claims 1-8 are pending in this application

### **Information Disclosure Statement**

2. The Information Disclosure Statement (IDS) filed on 01/25/2006 has been received and entered. The references cited on the PTO-1449 Form has been considered by the examiner and a copy is attached to the instant office action.

### **Election Acknowledged**

3. During a telephonic conversation with Bryan P. Stanley on September 24, 2007, a provisional election was made to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8 are, drawn to a stable solution formulation consisting essentially of: a therapeutically effective amount of carprofen, polyols, stabilizing agents and co-solvent.

Group II, claim(s) 9-26 are, drawn to a method of treating pain and/or inflammation in a warm blooded non-human animals comprising administering to the animal a solution formulation of the composition.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common therapeutically effective amount of drug is the carprofen. This drug carprofen cannot be a special feature under PCT Rule 13.2 because the drug is shown in the prior art. US 2001/0002401 A1; 2002/0192288 A1 teaches the same therapeutically effective drug for treatment of early states of degeneration of articular cartilage or subchondral bone in the joints of a mammal or for long-lasting pain relief from mucosal damage.

Applicant is reminded that upon the cancellation of claims to an non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accomplished by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102/103***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated or alternatively, as being unpatentable over Ogorka et al. (US 2001/0033866 A1) or Wagner et al (US 5,948,416).

The claims are drawn to a stable solution formulation consisting essentially a therapeutically effective amount of carprofen, one or more polyols, stabilizing agents and co-solvents. Claims requires the amount of each component present in the range 1-500g/L of carprofen, 20 to 998g/L polyols and 0 to 500g/L co-solvents.

Ogorka (US '866) discloses a pharmaceutical formulation comprising active ingredient such as carprofen. The active agent may present in a range of 50 to 90% by weight (see abstract and para 0030), polyols like polyethylene glycol may present in a range of 0.1% to 1% by weight of active ingredient (see para 0049), stabilizing agent such as alpha tocopherol present in the range of 0.01-5% by weight and purified water. Furthermore, US'866 discloses that the patented therapeutic formulation would be useful treatment of patients with mild to moderately severe dementia of the Alzheimer disease.

Wagner discloses a cosmetic composition comprising about 0.001% to about 20% of an active ingredient (carprofen, see col. 4, lines 50), 0.1% to about 20% of polyhydroxy alcohols such as sorbitol, glycerol, propylene glycol and polyethylene glycol (see col. 12, lines 65+), stabilizers such as tocopherol and co-solvents such as water in various amounts. And further, the compositions are useful for delivering a wide variety of active ingredients to the skin.

The daily dosages are well suggested and minor variations of specific dosage regimen (e.g., variation of carprofen, polyols, stabilizing agents and co-solvents etc) can be easily titrated and obtained in order to determine best outcomes, and it is considered to be routine practice especially having dosage suggestions by Ogorka's patent. Even if the anticipation were not clearly made, at least the modification would not render the claimed invention patentably distinct, because it is obvious to make such modification, well within the skilled level of the artisan and considered to be a routine optimization commonly practiced in the art, as evidenced by cited references.

### ***Conclusion***

1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala  
Examiner  
Art Unit 1618



Zohreh Fay  
Primary Examiner  
Art Unit 1618

